Message

From: Lindstrom, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=04BF7CF26AA44CE29763FBC1C1B2338E-LINDSTROM, ANDREW]
Sent: 3/24/2017 6:35:21 PM
To: Ducatman, Alan [aducatman@hsc.wvu.edu]
Subject: RE: RE:

Alan,

Thank you for your interest in this manuscript. We're not really in a rush with this so please don't feel compelled to address anything immediately. We're still very much in the initial stages of thinking about this so your point about including other replacements like ADONA is very much worth considering.
The REACH dossier for ADONA is here: https://echa.europa.eu/registration-dossier/-/registered-dossier/2602 but I'm not sure if information on other chemicals is available through REACH.

Any ideas you have about this issue and writing this manuscript will be very helpful.

From what I've read (and the way I remember it here within EPA at the time), I think the need to drop PFOA and embrace a new alternative (GenX) was one of the major drivers for the genesis of the Stewardship Program. I believe that the superficial evaluation that EPA did for GenX was motivated by the need for both parties to make progress and achieve some kind of resolution during a time of crisis.

While I can't prove it, I've always felt that EPA essentially made a deal with the PFAS producers that boiled down to saying "if you guys stop making long-chain PFAS, we'll stop hounding you on this issue." I don't think we did our due diligence on the review of most of the replacement PFAS, and at the time GenX needed to be accepted to demonstrate a plausible resolution of the entire issue. Sharon Lerner summarizes this very well in this article: https://theintercept.com/2015/08/20/teflon-toxin-dupont-slipped-past-epa/.

The problem was that GenX (and the other replacements) was nowhere near being a satisfactory solution. It was a stopgap temporary political move that gave the appearance of a satisfactory resolution. But the real problem was (and continues to be) TSCA and our willingness to allow corporations to foist the responsibility of chemical review and safety onto a beleaguered agency like the EPA.

I am very eager to work with you in any capacity because you are at the heart of our unresolved national PFOA and GenX crisis. USEPA should be heading a focused effort to help the members of your community but we are falling far short of what we should be doing to help.

My group has measured GenX in the surface water downwind of the plant in Ohio at concentrations exceeding 100 ng/L. The full range of PFOA and GenX contamination is not known. We have a lot of work to do.

Thank you,

Andy

From: Ducatman, Alan [mailto:aducatman@hsc.wvu.edu]
Sent: Thursday, March 23, 2017 5:12 PM
To: Lindstrom, Andrew <Lindstrom.Andrew@epa.gov>
Subject: RE: RE:

Hello Andrew:

1. Thank you! Yes, I am interested to help. I will read this carefully and get back to you. (I am traveling this weekend, so, it could be as late as Monday or Tuesday. Is that OK?).

2. A question. GenX only? You know much more than I about the new chemicals than most people, including the 3M product line such as Dyneon ADONA. Are they also of concern? (maybe when I drill down into this effort, they will be there).

3. Based on differences in expertise, I want to be modest up front about how much my expertise will add at this early stage of knowledge. It is not that clear to me that a physician can contribute at the same level of granularity as you and Gloria, before there is a lot of human health data to dig into (yet).

   For sure, I will try! One step at a time.

From: Lindstrom, Andrew [mailto:Lindstrom.Andrew@epa.gov]
Sent: Thursday, March 23, 2017 3:57 PM
To: Ducatman, Alan <aducatman@hsc.wvu.edu>
Subject: FW: RE:

Alan,

I hope you are doing well.

Gloria and I are probably going to help write a paper about the implications GenX as an unquestioned substitute for PFOA.

I've attached a very rough draft of what we're working on and we'd like to invite you to join in if you are interested.

I floated this idea with Arlene during some recent GSPI communication and she was very receptive to the idea and wanted to get other coauthors involved.

I agreed to take a crack on a first draft, and with what we've written so far I'm becoming more and more convinced that this would be a useful paper.

Ultimately, I'm not sure if government folks like Gloria and I will be able to be authors, but I'm going to try. If not, we'll have at least helped to put something useful together.

Please take a look at the draft and let me know what you think. Gloria will be working on summarizing the GenX carcinogenicity data this weekend. I'll be able to fill in the TSCA and regulatory stuff a little later on. I'll also be doing a summary of the reported occurrence worldwide.

I'm very concerned that there are now reports of GenX in surface and drinking water in the US and Europe.

Take care,

Andy

From: Arlene Blum [mailto:arleneb@lmi.net]
Sent: Wednesday, March 01, 2017 8:14 AM
To: Lindstrom, Andrew <Lindstrom.Andrew@epa.gov>
Cc: Tom Bruton <tom@greensciencepolicy.org>
Subject: Re: RE:

Thank you for your message and excellent idea and your willingness to write a first draft
I will start by sharing with Tom and we should all think about who else might be good co-authors

Good to include David from EW G and Lauren from silent spring and perhaps someone from Harvard as they have good communications offices and can help get the word out when the article is published
Philippe is always good
Might you have other suggestions about coauthors Who have expertise up about GenX

We will need to think about the journal also

Sorry You missed the call yesterday I hope you're feeling better

Arlene Blum, PhD
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On Mar 1, 2017, at 5:19 AM, Lindstrom, Andrew <Lindstrom.Andrew@epa.gov> wrote:

> Arlene,
>
> Yes, please share this with anyone who may be interested.
>
> If folks are interested, I think I can help write this but (as always) I may not be able to be listed as an author.
>
> This would pretty much be a policy piece asking the question - why was GenX allowed to be take the place of PFOA when they are so similar? And what do we need to do about it now?
>
> A complication will be that this replacement was accepted before new TSCA was put in place. So maybe it also illustrates why old TSCA was bad but it also gives the opportunity to explore whether new TCSA would allow the same substitution.
>
> To me the bottom line should be alerting folks to the fact that GenX is very similar to PFOA and it is being used and folks are being exposed. And our policies said it was OK.
>
> Thank you,
>
> Andy

From: Arlene Blum [mailto:arleneb@lmi.net]
Sent: Monday, February 27, 2017 5:27 PM
To: Lindstrom, Andrew <Lindstrom.Andrew@epa.gov>
Subject: Re:

Great idea!
Would you be able to write it?
Would you want help from folks on our pfas call?
Ok to share your idea with tom who is now working with us?

Arlene Blum, PhD
Green Science Policy Institute
Office: 510 898 1739
Ex. 6 Personal Privacy (PP)

www.greensciencepolicy.org

On Feb 27, 2017, at 1:41 PM, Lindstrom, Andrew <Lindstrom.Andrew@epa.gov> wrote:

Arlene,

We may have an idea for a new paper that our group could consider.

The basic question is why GenX was approved to replace PFOA when it basically has all (or most) of the characteristics of PFOA?

You may have seen this article that came out over the weekend:

http://www.dispatch.com/news/20170225/replacement-chemical-for-c8-being-studied-amid-similar-health-concerns

GenX is basically showing up all over the place (Holland, Parkersburg, North Carolina) and its still pretty much has all of the concerns related to PFOA. So why and how did EPA approve its use?

This would be a policy paper, probably best written with the help of risk assessors and toxicologists. Sharon Learner wrote about this here: https://theintercept.com/2016/03/03/new-teflon-toxin-causes-cancer-in-lab-animals/. But a group of scientists could (and should) probably cover this topic in much more detail.

Here is a possible outline for this kind of a paper:

GenX replacement for PFOA:

Chemical structure is different than PFOA, only obvious advantage is shorter biological half-life in some species.

But:

Like PFOA, does not break down in the environment.

And larger amounts may need to be used in industrial processes to achieve same effect as PFOA.

Not detected by routine analytical methods, so difficult to study environmental occurrence.

Toxicity issues for GenX (specifically cancer) are known:

Chronic bioassay in male and female rats published in peer-reviewed journal (this study may have been requested in the consent order with EPA)

Caused same 3 tumor types as PFOA (liver, testicular, pancreatic)

As stated in paper, these 3 types are also caused by some other PPAR-alpha activators that are unrelated to PFAS

In a letter to EPA, it was stated that the tumors are not relevant to human risk assessment because of lack of genotoxicity, the high dose at which tumors occur, and because these PPAR-alpha associated tumors are relevant to rats but not humans.

EPA apparently accepted this explanation, since no follow-up mode of action studies were requested and no other actions were required.

But for PFOA, there has already been extensive evaluation of the mode of action of these 3 tumor types.

EPA Guidelines for Carcinogen Risk Assessment include default assumptions:

One of default assumption is that tumors in animals are considered relevant to humans unless it is **conclusively** demonstrated that the mode of action is not relevant to humans.

Another default assumption is that low-dose extrapolation (i.e. a cancer slope factor approach) should be used unless mode of action studies conclusively demonstrate that the tumors occur through a threshold mechanism that is not relevant at low doses.

Mode of action studies of PFOA and GenX have not demonstrated that the 3 tumor types are **not** relevant to humans or that they occur only at high doses through a threshold mode of action.

The EPA Office of Water and NJ DWQI have developed slope factors for tumors caused by PFOA.

There appears to be a disconnect/inconsistency between different parts of USEPA on this issue.

The GenX chemical was approved for use without mode of action studies showing tumors are not relevant to humans.

However, if this chemical has been detected in environmental media (e.g. soil, water) and a health-based guidance or standard needs to be developed, EPA risk assessment guidelines require information on mode of action of tumors before a conclusion that they are not relevant to humans can be made.

Include some discussion of the more general issue of the approval of many PFAS replacements based on similarly limited data.

This whole issue is an example of what is wrong with TSCA (not sure if new TSCA could prevent this) and is discussed David Sedlak's recent editorial "Fool Me Once" http://pubs.acs.org/doi/abs/10.1021/acs.est.6b03367

What do you think?

Thank you very much,

Andy